

REMARKS

Upon entry of this amendment, claims 1-7 and 55-67 are pending. Claims 1, 25, and 55-57 are amended, claims 27-54 are canceled, and claims 58-67 are new. New claims 58-67 are supported in the specification, for example in paragraphs [0006], [0023]-[0026], [0031], [0037], and [0038] and in original claims 9-15. The amendment to claim 1 is supported at, for example, paragraphs [0037] and [0038].

35 U.S.C. § 112 Rejection

Reconsideration is respectfully requested of the rejection of claims 55-57 as not satisfying the requirements of 35 U.S.C. § 112, second paragraph. Without conceding the propriety of the rejection and to expedite prosecution, claim 55 has been amended to clarify that the water-soluble glass contains about 1-40 wt.% of a calcium component, about 5-65 wt.% of an alkali metal oxide component and about 20-94 wt.% of a glass former. Claims 56 and 57 have been amended to conform to the claim language of claim 55. Thus, amended claim 55 satisfies the requirements of 35 U.S.C. § 112, second paragraph.

35 U.S.C. § 102 Rejections

Claim 1 is directed to a calcium phosphate body wherein the body is a calcium phosphate agglomerate being a product of an agglomeration as an agglomeration of a plurality of water-soluble glass bodies is transformed into a plurality of calcium phosphate bodies by dissolution of said glass bodies and reaction of Ca^{2+} ions therefrom with PO_4^{3-} and OH^- . Further, the calcium phosphate agglomerate has a shape that is substantially the same as that of the agglomeration of the plurality of water-soluble glass bodies.

1. Shimp et al. (U.S. Patent No. 5,702,677)

Reconsideration is requested of the rejection of claims 1-4 and 6 as being anticipated by Shimp et al. under 35 U.S.C. § 102.

Claim 1 is directed to a calcium phosphate agglomerate which a) is a product of an agglomeration formed as an agglomeration of water-soluble glass bodies transforms into an agglomeration of calcium phosphate bodies, and b) has a shape that is substantially the same as that of the agglomeration of the plurality of water-soluble glass bodies from which the

agglomerate is formed. The water-solubility and transformation aspects of (a) are explained in the specification:

[0019] In general, the calcium phosphate bodies of the present invention are derived from a water-soluble glass body containing calcium. When the glass is immersed in or otherwise contacted with an aqueous phosphate solution, the glass dissolves, thereby releasing Ca^{2+} ions into the aqueous phosphate solution. In this solution, Ca^{2+} ions react with PO_4^{3-} and OH^- ions to form calcium phosphate which has a relatively low solubility limit in the aqueous phosphate solution. As the dissolution of the glass proceeds, the concentration of calcium phosphate increases in the solution until the solubility limit of calcium phosphate is exceeded and, as a consequence, calcium phosphate is deposited as a porous calcium phosphate layer on the outer surface of the water-soluble glass body. The formation of this porous calcium phosphate layer on the water-soluble glass body, however, does not prevent further dissolution of the water-soluble glass. Rather, the glass continues to dissolve and, as it does, the thickness of the porous calcium phosphate layer increases. Eventually, the water-soluble glass is completely dissolved, leaving only a porous calcium phosphate body.

In contrast, the Shimp particles are formed by agglomerating hydroxyapatite powder particles in water and are not formed by the transformation of an agglomeration of water-soluble glass bodies. And by virtue of Shimp's preparation method and absence of water-soluble glass bodies, it is therefore not possible for Shimp's hydroxyapatite particles to have a shape that is "substantially the same as that of the agglomeration of the plurality of water-soluble glass bodies" as required by claim 1. So neither (a) nor (b) are disclosed or suggested by Shimp. These are express requirements that cannot be ignored in assessing patentability. Additionally, new claims 58-65 are dependent on claim 1, incorporate all the requirements of claim 1 and are patentable for similar reasons as claim 1. Thus, claim 1-4, 6, and 58-65 are not anticipated by the Shimp reference.

2. Day et al. (U.S. Patent No. 6,358,531)

Reconsideration is requested of the rejection of claims 1-7 and 55-57 as being anticipated by Day et al. under 35 U.S.C. § 102. Day et al. disclose calcium phosphate *spheres* prepared

from alkali borate glass microspheres or irregular particles having a size from about 5 microns to about 1000 microns.¹

Claim 1

In contrast to Day et al.'s spheres, claim 1 requires an *agglomerate* of a plurality of calcium phosphate bodies. To bridge this gap between spheres and agglomerate, the Office asserts that Day et al.'s process would have inherently resulted in an agglomerate. But this is not the case. In fact, the Day et al. disclosure describes that *discrete* particles are formed. For example, the description of Figures 7, 8, and 9 refers to shells, concentric shell, and porous, homogeneous gels. This description does not describe an agglomerate. Moreover, Figures 4, 7, 8 and 9 show discrete microspheres, and not an agglomerate of phosphate bodies. Since the disclosure and figures show non-agglomeration, the inherency asserted by the Office is not supported, and in fact is proven to be absent. For there to be inherency, the Office must present evidence that the missing element is *necessarily* present in the reference (MPEP 2112.7):

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). . . .

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was

¹ See U.S. Patent No. 6,358,531 at column 6, lines 7-11.

biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

Here objective evidence and cogent technical reasoning support a conclusion that there is no inherency because the Day et al. process is shown to yield non-agglomerates. So it certainly cannot be said the Day et al. process would have *necessarily* produced agglomerates.

Claims 58-65 are dependent on claim 1, incorporate all the requirements of claim 1 and are patentable for similar reasons to claim 1. Thus, claims 1-7 and 58-65 are not anticipated by the Day reference.

Claim 55

Claim 55 is directed to regular or irregular particles of hydroxyapatite prepared from molded or crushed water-soluble glass. The water-soluble glass contains about 1-40 wt.% of a calcium component, about 5-65 wt.% of an alkali metal oxide component and about 20-94 wt.% of a glass former, provided it is other than glass containing 20-35 wt% CaO, 20-35 wt.% Na₂O, 0-10 wt.% P₂O₅ and 30-50 wt.% B₂O₃ transformed in a phosphate solution at a temperature of less than about 100°C. Further, the hydroxyapatite particle of claim 55 has substantially the same shape as the molded water-soluble glass.

The Day reference is described above and does not disclose calcium phosphate bodies prepared transforming molded water-soluble glass particles. Because the Day reference does not describe or use molded water-soluble glass in the transformation, the particles produced in the Day reference cannot have substantially the same shape as the molded water-soluble glass used in the transformation. Thus, claims 55-57 and the claims that depend therefrom are not anticipated by the Day reference.

3. Tadic et al.

Reconsideration is requested of the rejection of claims 1-4 as being anticipated by Tadic et al. under 35 U.S.C. § 102. Tadic et al. disclose carbonated calcium phosphates having reproducible crystallinity and carbonate content. This process provides calcium phosphates from

mixing ammonium phosphate, ammonium carbonate, and calcium nitrate and rapidly filtering off the product before it can crystallize.

Claim 1 requires that the shape of the calcium phosphate body be substantially the same as that of the agglomeration of a plurality of water-soluble glass bodies used in the transformation. Since the particles described in Tadic et al. were prepared by reacting ammonium phosphate, ammonium carbonate, and calcium nitrate and filtering off the resulting precipitated particles and are not prepared by transforming an agglomeration of a plurality of water-soluble glass bodies, the particles of Tadic et al. cannot have substantially the same shape as the shape of the agglomeration of a plurality of water-soluble glass bodies as required by claim 1. Since Tadic et al. do not disclose all the elements of claim 1, claim 1 and the claims that depend therefrom are not anticipated by Tadic et al.

4. Paul et al.

Reconsideration is requested of the rejection of claims 1-7 as being anticipated by Paul et al. under 35 U.S.C. § 102. Paul et al. disclose preparation of hydroxyapatite powder by precipitation from a mixture of calcium hydroxide and phosphoric acid. The fine hydroxyapatite powders prepared were then mixed with chitosan in a dispersion media to form spheres having a diameter of 212 to 1000 microns. Glutaraldehyde was then added to harden the spheres that formed.

The Office takes the position that "the packed spheres disclosed on page 385, second column, lines 12-16, forming a matrix, meet the limitation."² However, Applicants do not agree with this interpretation. The reference says that the "[s]pheres, when packed together, form a matrix with uniform pores between particles"³ While the term matrix can mean the connective substance between elements, another and more apt definition in this situation is "something resembling an array, as in the regular formation of elements into columns and rows."⁴ In this case, the spheres are packed together and the spaces between the packed spheres form pores, so the bone can grow into the packed spheres, thus providing the connective tissue. Thus, this matrix is not an agglomerate as required by the claims.

² See Office action dated December 10, 2007 at pages 4-5.

³ Paul et al. at page 385.

⁴ American Heritage Dictionary.

Further, claim 1 requires that the shape of the calcium phosphate body be substantially the same as the shape of the agglomeration of a plurality of water-soluble glass bodies used in the transformation. Paul et al. describe hydroxyapatite particles made by precipitation from a solution of calcium hydroxide and phosphoric acid and then formed into spheres by contacting the hydroxyapatite particles with a chitosan solution, dispersing this hydroxyapatite/chitosan slurry in an organic dispersion medium to form spheres and then adding glutaraldehyde to harden the resulting spheres. Because the spheres described by Paul et al. were not prepared by transforming an agglomeration of a plurality of water-soluble glass bodies in a phosphate solution, these spheres cannot have substantially the same shape as the shape of the agglomeration of a plurality of water-soluble glass bodies as required by claim 1. Thus, claims 1-7 and the claims that depend therefrom are not anticipated by Paul et al. under 35 U.S.C. § 102.

Rejoinder

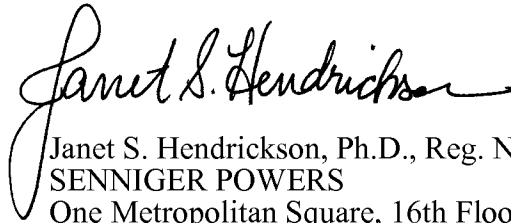
In this case, the restriction of the claims is not proper. It is noted that the claims from Groups I and II are classified in the same class (423) and the same subclass (308). Thus, the examination of the claims of these two groups can be made without serious burden.

CONCLUSION

Applicant submits that the present application is in condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

Respectfully submitted,

A handwritten signature in black ink, reading "Janet S. Hendrickson", with a stylized flourish at the end.

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